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President

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Dockets Management Branch (HFA-305)
U. S. Food and Drug Administration
5630 Fishers Lane
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RE: Docket No. 02N-0276 and Docket No. 02N-0278

On behalf of the members of the Foodservice & Packaging Institute, Inc. (FPI), the trade association for manufacturers and suppliers of single-use packaging used in foodservice applications, I am writing to provide our comments on the Agency's proposed "Registration of Food Facilities" and "Prior Notice of Imported Food" rules, both of which are issued under implementation of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

Regarding the definition of "food" contained in both the proposed "Registration of Food Facilities" rule, and "Prior Notice of Imported Foods" rule, FPI raises four points:

1. In regard to packaging, the rules do not conform to existing law.

In proposed "Food Facilities Registration" Subpart 1.227, and in a similar reference in the proposed "Prior Notice of Imported Food" rule, FDA proposes to include as examples of food as defined in Section 201(f) of the act "substances that migrate into food from food packaging and other articles that contact food". The proposal further states that "Substances that migrate into food from food packaging include immediate food packaging or components of immediate food packaging that are intended for food use."

The Agency's proposed interpretation of the definition of food, then, would include on the one hand, "packaging substances that migrate into food", while on the other hand it cites food contact ("all immediate food packaging or components of immediate food packaging that are intended for food use") as the rationale for packaging inclusion. The marriage of these two concepts presupposes that direct-food contact equals migration. This reading is contrary to, and does not conform with, existing FDA law.

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The Food, Drug and Cosmetics Act only triggers action when direct-food contact substances and materials are *proven* to migrate into food, and are shown to be harmful.

The Agency's rationale for including direct-food contact packaging in the Food Facilities Rule pre-supposes, first, that direct-food contact equals migration, and second, that such contact equals harm. Such supposition is at odds with the language of the Food Additive Amendment of the governing Food, Drug and Cosmetics Act statute.

2. The proposed rules are directly in opposition to Congressional Intent as expressed in the record of the Bioterriroism Act

Because of the Food Additive Amendment language conflict referenced above, Congress, in its deliberations on the Bioterrorism Act, specifically stated that it did not intend to have food-related portions of the Act apply to food packaging (*Congressional Record*, May 24, 2002, Remarks by Rep. John Shimkus (R-Ill.). The Agency in its proposed rule making has ignored this legislative history.

3. Proposed "Regulation of Food Facilities" Subpart 1.226 Exemption of "De minimis Activity" as applied to food-contact packaging

Several issues arise:

A. Why are foreign facilities exempt "if (packaging) from these facilities undergoes further manufacturing/processing by another foreign facility outside the United States"....but U.S. facilities do not receive benefit of the same exemption?
B. There needs to be a much clearer definition of "de minimis nature" of "further processing" other than the adding a label or plastic carrier rings examples cited in the proposal.

   For example, a packaging manufacturer might import basic stock paperboard from Asia, ship it to another company that adds coating to the paper, then take that coated paper and send it to another company for printing, who then sends the coated, printed stock on to a converter that turns it into anything from ice cream cartons to coffee cups that are sent to a food company for filling with ice cream or to a distributor for use in a restaurant. Each of these operations can make a case that it is performing "de minimis activity" and should be exempted.

FPI believes that the intent of the rule is that any activity before the final former/filler/sealer of the food product is, and should be, exempt. Further, we believe our position is in keeping with the intent of Congress in creating the Bioterrorism Act.

4. **The Restaurant Exemption**

In the proposed "Food Facilities Registration" Subpart 1.227 (c) (10), the rule exempts restaurant facilities of various kinds from compliance apparently because they sell food directly to consumers for immediate consumption.

Using that same logic, packaging used directly by consumers during immediate consumption, i.e. single-use foodservice packaging, should also be exempt.

If one of the stated intents of the proposal is to establish a trail for tracking a bioterriorism incident, and our packaging products would be presumed to be part of that trail because of their direct-food-contact nature, why would the Agency want to exempt facilities that use 99% of all single-use foodservice packaging? What good does it do to track where single-use food-contact products are made....but not where they are used?

If FDA is going to find evidence of contamination, that evidence is most likely going to come from a person getting sick who has used the product. And where have they used it?: In a restaurant! If the Agency exempts restaurants, at least with our products, you have left out a major player in the evidence chain.

Again, we do not feel that Congress intended to include the typical single-use Take Out food-contact packaging item in the Bioterrorism Act because Members realized that the dwell time use of such packaging is usually 15 or 20 minutes or less. Also, we expect Congress realized the folly of trying to force registration of the hundreds of thousands of restaurants, institutional feeding venues and push carts where such packaging is used. That is just one more reason why Congress said it did not intend to include food-contact packaging under the Act!

In closing, the members of the Foodservice & Packaging Institute wish to assure the FDA that, no matter what compliance measures are adopted, we pledge to join the FDA, and indeed all agencies of our government, to do all that we can to assure American consumers that our facilities and our products are safe, sanitary and protected from acts of bioterrorism.

Thank you for your consideration of our views.

John R. Burke